

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of) **MAIL STOP AF**
Ken Tatebe et al.)
Application No.: 10/551,279) Group Art Unit: 1797
Filing Date: September 27, 2005) Examiner: Dean P. Kwak
Title: TEST PAPER AND POROUS) Confirmation No.: 1584
MEMBRANE)
)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Claims 1 and 4-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Application Publication No. 2001-165390, hereinafter the Japanese publication. Applicants respectfully request review of these rejections.

A. Claimed Subject Matter

Claims 1 and 6 are the only independent claims in this application. Claim 1 defines a test paper comprising a porous membrane, and Claim 6 defines a porous membrane.

The test paper at issue here is of the type in which a blood sample is applied to one surface of the paper, the sample percolates to the other surface (i.e., the measuring surface) of the test paper, and the color change of the measuring surface is measured by irradiating light on the measuring surface and determining the intensity of the reflected light. Such test papers are used, for example, to determine a blood glucose level.

As discussed, for example, in the paragraphs bridging pages 12 and 13 and pages 20 and 21 of the specification, the inventors here have recognized that direct light reflected at the measurement surface of the test paper represents a noise when undergoing such a reflection absorbance measurement. In this regard, the application discloses modifying the surface glossiness of the measurement surface by, for example, the surface treatments disclosed in the paragraph bridging pages 37 and 38 of the specification. As further

discussed in the first full paragraph on page 39 of the specification, the experimental results discussed in the application indicate that when the surface glossiness of the measuring surface according to JIS Z8741 is not higher than 11, the measuring accuracy in a high range of blood glucose level can be improved.

Accordingly, both the test paper recited in independent Claim 1 and the porous membrane recited in independent Claim 6 includes a layer having a surface with a glossiness according to JIS Z8741 of not higher than 11.

B. The Examiner's Position

The Official Action asserts that the Japanese publication discloses a prior art test paper and porous membrane having several, but not all, of the claimed features. For example, the Japanese publication does not discuss the glossiness of any of the surfaces of the prior art test paper. The Examiner further asserts that it would have been obvious to modify the prior art test paper to have all of the claimed features. For example, the Examiner asserts that it would have been obvious to modify the second layer of the prior art test paper to have a surface glossiness according to JIS Z8741 not higher than 11.

More specifically, the Examiner asserts that an ordinarily skilled artisan would select a material for the prior art test paper that would work best for its intended purpose, and also states that the surface glossiness of the test paper depends on the selected material for the test paper. Based on these assertions, the Examiner concludes that the surface glossiness of the prior art test paper was recognized in the prior art as a result effective variable, and that modifying the prior art test paper to have a surface glossiness as recited in this application would therefore have been obvious to an ordinarily skilled artisan.

As discussed below, the Examiner's position is clearly erroneous as it is premised upon an improper characterization of the surface glossiness of the prior art test paper as a result effective variable. The Examiner has therefore failed to establish a *prima facie* case of obviousness of the test paper recited in independent Claim 1 or the porous membrane recited in independent Claim 6.

C. Discussion

As discussed in the Manual of Patent Examining Procedure § 2144.05, "(a) particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." Here, the Examiner has only alleged that the chosen material itself is recognized as a result effective variable. Additionally, while the Examiner has generally alleged that surface glossiness is material-dependent, the Examiner has provided no evidence that the glossiness is dependent solely on the type of material chosen for the test paper.

Even assuming the material chosen for the prior art test paper is a result effective variable, and the test paper's glossiness is influenced by the chosen material, it does not follow that the surface glossiness of the test paper is also a result effective variable. For example, an ordinarily skilled artisan would recognize that the surface glossiness of the test paper is influenced by not only the chosen material, but also any surface treatments, if any, performed on the prior art test paper.

Moreover, the Examiner has not established that the test paper material selection only influences glossiness. Indeed, the test paper material likely influences a variety of characteristics of the test paper, and so it is beyond reasonable to assume that the selection of test paper would be done solely with an eye to optimizing glossiness. Indeed, the discussion of the prior art test paper makes no mention of its surface glossiness, much less treating the material to modify its surface glossiness, and the Examiner has provided no evidence or rationale for concluding that the prior art test paper, even if optimized by an ordinarily skilled artisan by selecting an optimum material, would have had a surface glossiness in the recited range.

For the above reasons, the Examiner has committed clear error in failing to establish that the surface glossiness of the prior art test paper was recognized as a result effect variable. Accordingly, the Examiner has not established a *prima facie* case of obviousness in the rejections under 35 U.S.C. § 103(a). Therefore, the outstanding rejections under 35

U.S.C. § 103(a) are improper and should be withdrawn.

Respectfully submitted,

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Date: September 10, 2010

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